Consolidated text of the Rulebook on more detailed conditions for import of medical devices that are not registered includes the following:

1. Rulebook on more detailed conditions for import of medical devices that are not registered ("Official Gazette of Montenegro" No 073/22 from 12 July 2022),

2. Rulebook on amendments to the Rulebook on more detailed conditions for import of medical devices that are not registered ("Official Gazette of Montenegro", No 126/22 from 18 November 2022) in which their date of entry into force is provided.

RULEBOOK ON MORE DETAILED CONDITIONS FOR IMPORT OF MEDICAL DEVICES THAT ARE NOT REGISTERED

("Official Gazette of Montenegro", No 073/22 from 12 July 2022 and No 126/22 from 18 November 2022)

Subject

Article 1

This Rulebook prescribes more detailed conditions for import of medical devices that are not registered (hereinafter: unregistered medical devices).

Use of gender sensitive language

Article 2

Terms used in this Rulebook for natural persons in the masculine gender shall mean the same terms in the feminine gender.

Expressions

Article 3

Terms used in this Rulebook shall have the following meaning:
1) **Declaration of Conformity** of a medical device (hereinafter: Declaration of Conformity) is a document by which the manufacturer confirms that the medical device complies with the basic requirements;
2) **principal investigator** is a qualified person responsible for conducting the clinical investigation at the site of the clinical investigation. If the clinical investigation is conducted by a team of individuals at the clinical investigation site, principal investigator is responsible for the performance of the team;
3) **in vitro diagnostic medical device** is any medical device that is a reagent, reagent product, calibrator, control material, reagent kit, instrument, apparatus, equipment, software or system used alone, or in combination, intended by the manufacturer for use under in vitro conditions for the examination of samples, including donations of blood and tissues of human origin, solely or mainly to obtain information relating to:
- physiological, or pathological functions, or conditions;
- congenital physical, or mental anomalies;
- predispositions to a health condition, or illness;

- determining safety and compatibility with the potential recipient;
- predicting responses, or reactions to treatment;
- defining, or monitoring therapeutic measures.

Sample containers are considered the in vitro diagnostic medical device. Sample containers are vacuum, or non-vacuum type medical devices that are specifically intended by the manufacturer for the primary holding and storage of samples obtained from human body for the purpose of in vitro diagnostic testing.

Products for general laboratory use are not considered in vitro diagnostic medical devices, unless, due to their characteristics, those products are specifically intended by the manufacturer for use in in vitro diagnostic testing;

4) **economic operator** is a manufacturer, an authorized representative of the manufacturer, wholesaler, or importer;

5) **document of conformity** of a medical device (hereinafter: document of conformity) means: declaration of conformity, investigation report, certificate, control certificate, or other document confirming compliance of medical device with basic requirements;

6) **clinical investigation** of a medical device (hereinafter: clinical investigation) means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

7) **conformity assessment** is any activity that determines whether a medical device, i.e. the process of manufacturing a medical device complies with prescribed technical requirements, i.e. with basic requirements of this law, in order to determine that the medical device is safe and that it operates in accordance with its intended purpose;

8) **performance of a medical device** is an ability of the medical device to achieve its intended purpose as claimed by the manufacturer;

8a) Clinical investigation plan - CIP (hereinafter: protocol) is a document that determines basic principles, objectives, design, proposed analyses, methodology, supervision, conduction and records of a clinical investigation;

9) **fully refurbishing** is a complete rebuilding of a medical device already placed on the market, or put into service, or making of a new device from used devices, to bring it into conformity with basic requirements, combined with the assignment of a new lifetime to the refurbished device;

10) **manufacturer of a medical device** (hereinafter: manufacturer) is a legal or natural person responsible for its design, manufacture, packaging and labelling before placing it on the market under its own name, regardless of whether it performed these activities independently or other person performed them on its behalf;

11) **certificate of conformity** of a medical device (hereinafter: certificate of conformity) is an EC Certificate issued by a notified body, i.e. a certificate issued by a designated body that confirms that a medical device, or a group of medical devices of a certain manufacturer complies with basic requirements;

12) **Free sale certificate** is a document that proves that a medical device may be placed on the market in the country of the manufacture, or on the market of a member state of the European Economic Area (hereinafter: EEA member state);

13) **mark of conformity** of a medical device is a mark that the manufacturer places on the medical device and which confirms that the medical device complies with basic requirements. The mark of conformity may be a foreign mark of conformity (CE mark), or another mark of conformity of a medical device, in accordance with the law on technical regulations.

Import of an unregistered medical device

Article 4

Institute for Medicines and Medical Devices (hereinafter: Institute), in accordance with the Law on medical devices (hereinafter: Law), may approve the import of unregistered medical devices in following cases:
1) urgent medical need for a specific patient, or a group of patients, and there is no registered medical device on the market in Montenegro that can in an equally safe manner help the patient, or a group of patients in question;
2) not sufficient quantity of registered medical devices of appropriate use for the purpose of public health protection on the Montenegrin market;
3) research purposes;
4) clinical investigations;
5) natural hazards, or
6) other emergency situations.
Subject of import referred to in the paragraph 1 of this Article may be unregistered medical devices which are donations, or humanitarian aid, as well as unregistered medical devices that were marketed, or used.

Import proposal and application submission

Article 5

Import of an unregistered medical device may be proposed by a health institution, a scientific research institution, a social care and children care institution that provide health care, a humanitarian organization, a state administration body responsible for defense affairs, a state administration body responsible for health affairs and a state administration body responsible for internal affairs (hereinafter: import proposer).
Legal person that has a wholesale authorization for medical devices (hereinafter: wholesaler) shall, in the name and on behalf of the import proposer submit an import application for unregistered medical device (hereinafter: application) to the Institute.

An application may be submitted for import of one unregistered medical device for purposes of several import proposers, or for several unregistered medical devices for the purposes of one import proposer.
Application shall be submitted on the Form published on the portal of the Institute.

Documentation for import of unregistered medical device

Article 6

Wholesaler shall submit the following documentation along with the application:
1) justified proposal for the import of unregistered medical device, signed by an authorized person of the import proposer, with the authorization that the wholesaler may carry out the import in the name and on behalf of the import proposer;
2) statement of the responsible person of the import proposer that the unregistered medical device will be used in accordance with the purpose stated in justified proposal from paragraph 1 point 1 of this Article;
3) declaration of conformity and/or certificate of conformity of an unregistered medical device or proof that equivalent safety and performance assessment has been carried out for

unregistered medical device for which no conformity assessment was carried out by a notified body, i.e. a manufacturer seated in the EEA member state;
4) Free sale certificate, or certificate issued by an authorized body ISO 13485 for class I medical devices, other in vitro diagnostic medical devices and class A in vitro diagnostic medical devices;
5) translation of instructions for use of unregistered medical device into Montenegrin and into languages that are in official use in Montenegro, signed by a medical doctor of appropriate specialty for the medical device that the patient uses independently;
6) pro-forma invoice of the supplier;
7) other information at the request of the Institute, in accordance with the Law.
Notwithstanding the paragraph 1 item 3 of this Article the certificate of conformity of an unregistered medical device should not be provided for a medical device of class I, other in vitro diagnostic medical devices and in vitro diagnostic medical devices of class A.
Equivalent safety and performance assessment referred to in paragraph 1 item 3 of this Article implies that a conformity assessment is carried out in a member state of the International Medical Device Regulators Forum.
Justified proposal for import referred to in paragraph 1 item 1 of this Article and the statement of the responsible person referred to in the paragraph 1 item 2 of this Article shall be submitted on forms published on the portal of the Institute.

Import for research purposes

Article 7

To import unregistered medical device for research purposes, in addition to the application and documentation referred to in the Article 6, paragraph 1 items, 3, 4, 6 i 7 of this Rulebook, the wholesale shall submit the following documentation:
1) statement of the authorized person of the import proposer that conducts the research:
- that unregistered medical device will be used in research purposes only,
- that unregistered medical device will not be used in clinical investigations, i.e., that it will not be used in patients,
- that the unregistered medical device will not be used for commercial purposes;
2) proof that the import proposer is authorized to conduct research activity.
Quantity of unregistered medical device referred to in paragraph 1 of this Article should correspond to needs of the research work.

Import for clinical investigation

Article 8

To import unregistered medical device for clinical investigation, in addition to the application the wholesaler shall submit the following documentation:
1) list with names and quantity of unregistered medical devices which the import authorization is applied for;
2) statement of principal investigator that unregistered medical devices referred to in the item 1 of this paragraph is necessary to conduct the clinical investigation;
3) other information at the request of the Institute, in accordance with the Law.

Import in case of natural hazards or other emergency situations

Article 9

To import unregistered medical device in case of natural disasters or other emergency situations, in addition to the application and documentation referred to in the Article 6, paragraph 1, items 3 to 7 of this Rulebook, the wholesaler shall submit a list with names and quantity of necessary unregistered medical devices, which is compiled by the competent authority.

Import of unregistered medical device of animal origin

Article 10

To import unregistered medical device of animal origin, in addition to the application and documentation referred to in the Article 6 of this Rulebook, the wholesaler shall submit a manufacturer's confirmation that the unregistered medical device does not contain specific risk materials related to the transmission of spongiform encephalopathy (TSE), i.e., that it does not originate from them.
To import unregistered medical device that contains prescribed specific risk materials of animal origin, in addition to the application and documentation referred to in the Article 6 of this Rulebook, the wholesaler shall submit proof of the absence of the risk of transmissible spongiform encephalopathy (TSE).
Evidence referred to in paragraph 2 of this Article may be a manufacturer's statement or a corresponding TSE certificate on the absence of the risk of transmissible spongiform encephalopathy.

Import of unregistered medical device that is a donation or humanitarian aid

Article 11

To import unregistered medical device that is a donation or humanitarian aid, in addition to the application and documentation referred to in the Article 6 paragraph 1 points 3 to 7 of this Rulebook, the wholesaler shall submit the following documentation:
1) - statement of responsible person of the import proposer that the unregistered medical device is in good condition, i.e., that it can be used in a manner that is safe for the patient, and which also contains information about the manufacturer, donor or provider of humanitarian aid, as well as the name and quantity of unregistered medical device that is the subject of a donation, or humanitarian aid;
2) – contract on the donation, or humanitarian aid, i.e., statement of the donor of the provider of humanitarian aid.

Import of unregistered medical devices that was marketed or used

Article 12

To import unregistered medical device that was marketed or used, in addition to the application and documentation referred to in the Article 6 of this Rulebook, the wholesaler shall submit the following documentation:
1) proof that the unregistered medical device has not expired, as well as proof of the intended purpose specified by the manufacturer;

2) proof of the service of an unregistered medical device performed by a person authorized for servicing;
3) proof that further servicing is provided;
4) proof that the unregistered medical device is not older than ten years.

Import of fully refurbished unregistered medical device

Article 13

To import unregistered medical device that was fully refurbished, in addition to the application and documentation referred to in the Article 6 of this Rulebook, the wholesaler shall submit a manufacturer's statement that the medical device was fully refurbished, with a new expiry date assigned.

Approval of the Institute

Article 14

Approval of import of unregistered medical device shall contain the following documentation:
1) data on the wholesaler;
2) purpose of approval of import;
3) data on the import proposer;
4) name of the unregistered medical device;
5) quantity of unregistered medical device.
Validity date referred to in the paragraph 1 of this Article is three months since the day of the issuance.
Excluded from paragraph 2 of this Article, approval of import of unregistered medical device for clinical investigations, as well as unregistered medical device purposefully used for a clinical trial of a medicine, including a non-interventional trial, is valid in the course of a clinical trial, in accordance with clinical trial protocol.

Entry into force

Article 15

This Rulebook shall enter into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro".

No: 5-040/22-1034/5
Podgorica, 11 July 2022
Minister,
Dragoslav Šćekić, sgd.